GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:3591
ANSWERED ON:12.12.2000
REGULATORY PROCESS FOR MEDICAL BIOTECHNOLOGY PRODUCTS
SUBODH MOHITE

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) whether the Government have revamped regulatory process for medical biotechnology products;

(b) if so, the details in this regard;

(c) whether the fast-track clearance mechanism has been put in place for plant biotechnology products; and

(d) if so, the details thereof and other measures adopted by the Government to solve the problems experienced in the field of medical biotechnology products ?

Answer

MINISTER OF STATE IN THE MINISTRY OF SCIENCE AND TECHNOLOGY (SHRI BACHI SINGH RAWAT)

(a) & (b) : The Department of Biotechnology has prepared with the help of experts guidelinesfor generating preclinical and clinical data for rDNA based medical biotechnology productslike vaccines, diagnostics and other biologicals. Implementation procedures are under consideration.The regulatory procedures for clearing biomedical products are likely to be hastened with these guidelines.

(c) : Regulatory guidelines for transgenic crops were made in August 1998 and further modified in September 1999. There is no fast-track mechanism evolved for clearance of transgenic crops, as all safety aspects are to be evaluated.

(d) : Series of interactive meetings have been organised amongst the industries, scientists/developers of the technologies for possible transfer of technologies. These have generated interest in the industry and some diagnostic technologies have been transferred.